



DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA-2020-0016]

Meeting to Implement Pandemic Response Voluntary Agreement Under Section 708 of the Defense Production Act

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Announcement of meeting; request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) will hold a meeting remotely via web conference to implement the Voluntary Agreement for the Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic. A portion of the meeting will be open to the public.

DATES: The meeting will take place on Thursday, December 16, 2021, from 2 to 4 p.m. Eastern Time (ET). The first portion of the meeting, from approximately 2 to 3 p.m. ET, will be open to the public.

Written comments for consideration at the meeting must be submitted and received by 12 p.m. ET on Wednesday, December 15, 2021. Follow-up comments must be received by 5 p.m. ET on Wednesday, December 23, 2021, to be considered.

ADDRESSES: The meeting will be held via web conference. Members of the public may view the public portion of the meeting online at:

[https://fema.zoomgov.com/j/1616569597?pwd=TEMzUzljZGR0YlJNVkVHbWlUUEN2Zz](https://fema.zoomgov.com/j/1616569597?pwd=TEMzUzljZGR0YlJNVkVHbWlUUEN2Zz09)

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Reasonable accommodations are available for people with disabilities. To request a reasonable accommodation, contact the person listed in the **FOR FURTHER**

INFORMATION CONTACT section below as soon as possible. Last minute requests will be accepted but may not be possible to fulfill.

To facilitate public participation, members of the public are invited to provide written comments on the issues to be considered at the meeting. The Meeting Objectives listed below outline these issues. Written comments must be identified by Docket ID FEMA-2020-0016, and submitted by one of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments.
- *Email:* FEMA Office of Response and Recovery, Office of Business, Industry, Infrastructure Integration, OB3I@fema.dhs.gov.

Instructions: All submissions must include the docket ID FEMA-2020-0016.

Comments received, including any personal information provided, may be posted without alteration at <https://www.regulations.gov>.

Docket: For access to the docket and to read comments received by FEMA, go to <https://www.regulations.gov> and search for Docket ID FEMA-2020-0016.

FOR FURTHER INFORMATION CONTACT: Robert Glenn, Office of Business, Industry, Infrastructure Integration, via email at OB3I@fema.dhs.gov or via phone at (202) 212-1666.

SUPPLEMENTARY INFORMATION: Notice of this meeting is provided as required by section 708(h)(8) of the Defense Production Act (DPA), 50 U.S.C. 4558(h)(8), and consistent with 44 CFR part 332.

The DPA authorizes the making of “voluntary agreements and plans of action” with representatives of industry, business, and other interests to help provide for the national defense.¹ The President’s authority to facilitate voluntary agreements with respect to responding to the spread of COVID-19 within the United States was delegated

¹ 50 U.S.C. 4558(c)(1).

to the Secretary of Homeland Security in Executive Order 13911.² The Secretary of Homeland Security further delegated this authority to the FEMA Administrator.³

On August 17, 2020, after the appropriate consultations with the Attorney General and the Chairman of the Federal Trade Commission, FEMA completed and published in the *Federal Register* a “Voluntary Agreement, Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic” (Voluntary Agreement).⁴ Unless terminated earlier, the Voluntary Agreement is effective until August 17, 2025, and may be extended subject to additional approval by the Attorney General after consultation with the Chairman of the Federal Trade Commission. The Agreement may be used to prepare for or respond to any pandemic, including COVID-19, during that time.

On December 7, 2020, the first plan of action under the Voluntary Agreement – the Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Personal Protective Equipment (PPE) to Respond to COVID-19 (PPE Plan of Action) – was finalized.⁵ The PPE Plan of Action established several subcommittees under the Voluntary Agreement, focusing on different aspects of the PPE Plan of Action.

On May 24, 2021, four additional plans of action under the Voluntary Agreement – the Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Diagnostic Test Kits and other Testing Components to respond to COVID-19, the Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Drug Products, Drug Substances, and Associated Medical

² 85 FR 18403 (Apr. 1, 2020).

³ DHS Delegation 09052, Rev. 00.1 (Apr. 1, 2020); DHS Delegation Number 09052 Rev. 00 (Jan. 3, 2017).

⁴ 85 FR 50035 (Aug. 17, 2020). The Attorney General, in consultation with the Chairman of the Federal Trade Commission, made the required finding that the purpose of the voluntary agreement may not reasonably be achieved through an agreement having less anticompetitive effects or without any voluntary agreement and published the finding in the *Federal Register* on the same day. 85 FR 50049 (Aug. 17, 2020).

⁵ See 85 FR 78869 (Dec. 7, 2020). See also 85 FR 79020 (Dec. 8, 2020).

Devices to respond to COVID-19, the Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Devices to respond to COVID-19, and the Plan of Action to Establish a National Strategy for the Manufacture, Allocation, and Distribution of Medical Gases to respond to COVID-19 – were finalized.⁶ These plans of action established several sub-committees under the Voluntary Agreement, focusing on different aspects of each plan of action.

On October 15, 2021, the sixth plan of action under the Voluntary Agreement – the Plan of Action to Establish a National Strategy for the Coordination of National Multimodal Healthcare Supply Chains to Respond to COVID-19 – was finalized.⁷ This plan of action established several sub-committees under the Voluntary Agreement, focusing on different transportation categories.

The meeting is chaired by the FEMA Administrator’s delegates from the Office of Response and Recovery (ORR) and Office of Policy and Program Analysis (OPPA), attended by the Attorney General’s delegates from the U.S. Department of Justice, and attended by the Chairman of the Federal Trade Commission’s delegates. In implementing the Voluntary Agreement, FEMA adheres to all procedural requirements of 50 U.S.C. 4558 and 44 CFR part 332.

Meeting Objectives: The objective of the meeting is to update the general public, and private industry partners, on the status of the Voluntary Agreement, the recently established National Multimodal Plan of Action, and other Plans of Action concerning PPE, Medical Devices, Medical Gases, Diagnostic Testing Kits, and Drug Products/Drug Substances.

Meeting Closed to the Public: By default, the DPA requires meetings held to implement a voluntary agreement or plan of action be open to the public.⁸ However,

⁶ See 86 FR 27894 (May 24, 2021). See also 86 FR 28851 (May 28, 2021).

⁷ See 86 FR 57444 (October 15, 2021).

⁸ See 50 U.S.C. 4558(h)(7).

attendance may be limited if the Sponsor⁹ of the Voluntary Agreement finds that the matter to be discussed at a meeting falls within the purview of matters described in 5 U.S.C. 552b(c). The Sponsor of the Voluntary Agreement, the FEMA Administrator, found that a portion of this meeting to implement the Voluntary Agreement involves matters which fall within the purview of matters described in 5 U.S.C. 552b(c) and that portion of the meeting will therefore be closed to the public.

Specifically, the meeting to implement the Voluntary Agreement may require participants to disclose trade secrets or commercial or financial information that is privileged or confidential. Disclosure of such information allows for meetings to be closed pursuant to 5 U.S.C. 552b(c)(4). In addition, the success of the Voluntary Agreement depends wholly on the willing and enthusiastic participation of private sector participants. Failure to close the meeting to the public could have a strong chilling effect on participation by the private sector and cause a substantial risk of premature public release of sensitive information. Such a release of sensitive information could result in participants withdrawing their support from the Voluntary Agreement and thus significantly frustrating the implementation of the Voluntary Agreement. Frustration of an agency's objective due to premature disclosure of information allows for the closure of a meeting pursuant to 5 U.S.C. 552b(c)(9)(B).

Deanne Criswell,

Administrator,

Federal Emergency Management Agency.

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⁹ “[T]he individual designated by the President in subsection (c)(2) [of section 708 of the DPA] to administer the voluntary agreement, or plan of action.” 50 U.S.C. 4558(h)(7).